California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

NOTICE OF MEETING AND AGENDA

Enforcement Committee and E-Pedigree Public Meeting

March 14, 2013

Contact Person: Laura Hendricks
(916) 574-7918

This committee meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Laura Hendricks at (916) 574-7918, by emailing laura.hendricks@dca.ca.gov or sending a written request to Ms. Hendricks at the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

DATE: March 14, 2013

PLACE: Sheraton Garden Grove
12221 Harbor Blvd.
Garden Grove, CA 92840

WEBCAST: http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml
(link to Webcast will not be available until 9:30 a.m. on March 14, 2013)
Please note: Webcast will run concurrently with the meeting.

This meeting may be cancelled without notice. For verification of the meeting, call (916) 574-7900 or access the Board's Web site at www.pharmacy.ca.gov.

Discussion and action may be taken on any item on the agenda. The committee may discuss agenda items in any order. Time limitations for discussion and comment will be determined by the Committee Chair.

Agenda

Call to Order **9:30 a.m.**

I. Enforcement Committee Matters:

a. Request from Walgreens to Store Prescription Records Older than Five Years Outside a Licensed Premises

b. Request from Walgreens to Establish Pharmacy Kiosks In Workplace Clinics

Meeting Materials will be available on the board's Web site at www.pharmacy.ca.gov by March 11, 2013

c. **Request from Kaiser for a Temporary Waiver of Secure Prescription Blank Prescribing Requirements for Controlled Substances in a Closed Health Care System**

d. **Board Comments Submitted in Response to the Federal Department of Justice, Drug Enforcement Administration's Notice of Proposed Rulemaking Related to Disposal of Controlled Substances [Docket No. DEA-316]**

e. **Proposed Statutory Provisions to Prevent a Wholesaler From Purchasing Prescription Medication from a Pharmacy When the Pharmacy Did Not Purchase the Medication from the Wholesaler**

II. Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication **10:30 a.m.**

a. **Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 Has Been Determined (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)**
b. **Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule**
c. **Discussion Concerning Elements for Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163**
d. **Discussion on the Certification Process to Comply with California's E-Pedigree Law**
e. **Discussion on the Use of Drop Shipments in an E-Pedigree System**
f. **General Discussion/Questions and Answers**

III. Closing Comments

IV. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

ADJOURNMENT **4 p.m.**

Agenda Item I(a)

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Item I(a): Request to Store Prescription Records Over Five Years Old Offsite

Background:

California has requirements that all pharmacy records be readily retrievable in the licensed premises, and open to inspection by the board. These records are generally required to be retained for at least three years.

California law also permits the offsite storage of records if an offsite waiver has been approved by the board.

Request:

Walgreens has requested that because CMS requires storage of records for 10 years, they would like the ability to store records older than five years offsite at a firm that specializes in records storage. The specific request follows this page.

A representative of Walgreens will attend this meeting to provide information about the request.

January 14, 2013

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Dear Ms. Herold,

Walgreens requests to be placed on the next Enforcement Committee on March 21, 2013. We are seeking a waiver for off-site retention of prescription records as stated in Section 1707 of Article 2 of Division 17 of Title 16 of the California Code or Regulations.

In order to comply with CMS recordkeeping requirements, Walgreens is looking to retain off-site in conjunction with Iron Mountain all prescription hard copy records that are older than 5 years. Iron Mountain is an information management company that manages assets, electronic records, document imaging, business records and secure shredding for organizations worldwide. Iron Mountain's facilities meet the requirements of National Archives of Records Administration (NARA) 36 Code of Federal Regulations Part 1234 as well as Federal Emergency Management Agency (FEMA) Continuity of Operations Plan (COOP) requirements.

These records will be retained for an additional 5 years to be in compliance with the CMS Medicare Prescription Drug Improvement and Modernization Act requirements to keep records for 10 years. Due to these special circumstances, we would like to appear before the Board to present this request.

Thank you for considering this waiver, and I look forward to meeting with the Board at the next meeting.

Please call me if you have any questions.

Sincerely,

Al Carter, Pharm.D.
Director, Professional Affairs
Walgreen Co.
200 Wilmot Rd., MS #2161
Deerfield, IL 60015
Phone 847-315-3940
Fax 847-315-3109
Al.Carter@Walgreens.com

Agenda Item I(b)

California State Board of Pharmacy
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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Item I (b): Request to Install an Automated Drug Delivery Device (or Kiosk) in Workplace Centers

Background:

Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate. The conditions are listed below in the highlighted segment of section 1713.

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

In 2009-10, Pharmacist Consultant Philip Burgess, on behalf of a manufacturer of one of these machines (Asteres), sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change). There was no further interest pursued by Asteres after the January 2010 meeting. Materials covering some of these discussions are provided in Attachment Agenda Ib.

<u>At this meeting:</u>

Walgreens has requested an opportunity to address the board to seek a waiver of 1713 to permit the use of an automated delivery device in a workplace setting, away from a pharmacy. A copy of this request follows this page.

Representatives of Walgreens will attend the meeting and provide the presentation.

January 18, 2011

Ms. Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Dear Ms. Herold,

Walgreens requests to be placed on the next Enforcement Committee on March 21, 2013. We are seeking a waiver to allow for the placement of an automated drug delivery device (kiosk) at a company worksite of which an inpatient clinic is located without an outpatient pharmacy. As stated in Section 1713 of Article 2 of Division 17 of Title 16 of the California Code or Regulations, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.

Walgreens would like to request the capability to place this automated delivery device on the campus of a worksite inpatient clinic to provide pharmacy services to these employees.

Thank you for considering this waiver, and I look forward to meeting with the Board at the next meeting.

Please call me if you have any questions.

Sincerely,

Al Carter, Pharm.D.
Director, Professional Affairs
Walgreen Co.
200 Wilmot Rd., MS #2161
Deerfield, IL 60015
Phone 847-315-3940
Fax 847-315-3109
Al.Carter@Walgreens.com

Ms. Herold:

On behalf of Asteres, we hereby request an appearance before the California Board of Pharmacy at the January 20/21 meeting in Sacramento.

The purpose of our appearance will be to seek approval for the installation of an automated prescription "pick up" system in a hospital environment whereby the unit is not directly attached to the pharmacy.

Upon review of Section 1713, we feel that the Board has regulatory authority to grant this request based upon Paragraph 1713 (b) which states in part:

"In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause. Subdivision (a) contains the language prohibiting the picking up of prescriptions from "any place not licensed as a retail pharmacy". We will be prepared to justify this action by the Board demonstrating how that the unit will be in a high-traffic, secure area on the hospital campus and that a telephone installation immediately adjacent to the unit will allow readily available access by the patient to a pharmacist for counseling.

Failing this argument, then we would request a specific waiver from Section 1713 (d) (6) requiring that "the device is located adjacent to the secure pharmacy area". We are prepared to have representatives appear from California hospitals to represent to the Board that by allowing flexibility in the placement of these "pick-up" devices on their campuses, that the net result will be to improve patient compliance and thereby improve patient care. Asteres will present past history to show to the Board that these devices can be installed in an area not adjacent to the pharmacy, yet in a secure manner..as well as in a manner where counseling by a pharmacist to the patient will be equally if not more readily available than in a standard retail environment..

Thank you for your consideration.

Phil

Philip P. Burgess, RPh, MBA
Philip Burgess Consulting, LLC
3800 N. Lake Shore Drive
Chicago, IL 60613
(773) 595-5990
www.philburgessconsulting.com

Title 16, California Code of Regulations

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be to or from Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision

(a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.

Authority cited: Sections 4005, 4075, and 4114 Business and Professions Code. Reference: Sections 4005, 4052, 4116 and 4117 Business and Professions Code.

Open Session

IX. Licensing Committee Report

a. Report of the Committee Meeting Held December 3, 2009

1. Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

Mr. Weisser provided that in 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. He stated that this was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Mr. Weisser explained that a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. He advised that the machine was to be located near – specifically adjacent -- to the physical area of the pharmacy.

Mr. Weisser provided that a number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive.

Mr. Weisser advised that this regulation was promulgated cautiously. He stated that throughout 2006, the board modified and adopted the regulation now in effect as section 1713. Mr. Weisser provided that in January 2007, the regulation actually took effect.

Mr. Weisser provided that during the meeting, the committee heard a presentation from Phil Burgess, representing Asteres, one vendor of these automated delivery devices. He stated that Mr. Burgess is seeking a waiver to the requirements in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. Mr. Weisser explained that in making the request, Mr. Burgess stated that they would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist.

Presentation - Phil Burgess and Mike de Bruin, Asteres

Phil Burgess, representing Asteres, provided an overview of ScriptCenter, a 24/7 automated pharmacy prescription pick-up machine including the registration and authorization process. He reviewed patient safety and security benefits and

added that ScriptCenter has successfully delivered over 450,000 prescriptions without one delivery error.

Mr. Burgess requested that the board waive regulation Section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals.

Board Discussion

Mr. Brooks sought clarification regarding how a pharmacy obtains a ScriptCenter machine.

Mike de Bruin provided that there are multiple methods of acquisition strategies.

Burgess provided that each machine will have a phone located adjacent to the machine to allow the patient to immediately contact the pharmacist.

Mr. Lippe asked if the patient will be charged a transaction fee.

Mr. Burgess provided that no transaction fee is charged.

Mr. de Bruin provided that the machine will collect the patient's insurance co-pay.

Ms. Herold sought clarification regarding if it is intended for the machine to be made available to both hospital staff and patients.

Mr. Burgess indicated that Asteres would like the machine to be available to both hospital staff and patients. He provided that only refill prescriptions would be filled and the machine would only be located on the hospital campus in a secure environment, not necessarily in a hospital.

Mr. Room asked if any machines have been installed outside of a hospital campus.

Mr. de Bruin provided that machines have been installed in other areas in other states.

Mr. Room provided that this request may not be granted under a Section 1713 waiver.

Discussion continued regarding the ScriptCenter system and its applicability to pharmacy law and Section 1713. Advantages and disadvantages of the system were evaluated. Concern was expressed that this process may depersonalize the pharmacist and prescription service. It was clarified that in the event a waiver is granted, the waiver would be granted to the licensed facility and not to Asteres.

Public Comment

Dr. Allan Schaggs, representing Catholic Healthcare West (CHW), provided that CHW would like to provide ScriptCenter as a service to their employees.

Dr. Castellblanch sought clarification regarding why the waiver is also being requested for patients.

Mr. Burgess provided that the machine can benefit the spouses of employees and children of employees.

Discussion continued regarding the request and the placement of the machine in a secure area on the hospital campus. Concern was expressed that the request does not specify placement of the machine.
Dr. Steve Gray, representing Kaiser Permanente, offered support for the ScriptsCenter concept. He encouraged the board to grant a waiver under Section 1713 (b) for employees and to consider further discussion of a waiver for other patients.

Mr. Weisser sought clarification regarding mail order prescriptions and patient requests for phone consultations with a pharmacist.

Dr. Gray provided that in the rare event that a patient does have a question, they can often get their questioned answered faster by calling a pharmacist than if they were to wait in line at a pharmacy.

Mr. Burgess provided that the ScriptsCenter machine allows for a pharmacist to be available to the patient when the adjacent pharmacy is closed during off hours.

Ms. Herold provided that pharmacies using such a device are required to provide immediate access to a telephone for patients to contact a 24-hour pharmacy in the event their pharmacy is closed.

Ms. Herold indicated that board staff will provide some guidelines to assist Asteres with providing the required clarification regarding their request.

There was no additional board discussion or public comment.

2. Final Review on Parameters for Recalls in Hospitals

Mr. Weisser provided that during the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall.

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Licensing Committee Report

Members:
Stan Weisser, RPh, Chairperson
Randy Kajioka, PharmD
Ramón Castellblanch, Public Member

IX. LICENSING COMMITTEE REPORT AND ACTION

a. Report of the Committee Meeting Held December 3, 2009

1. FOR DISCUSSION: Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

Attachment 1

Background

In 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. This was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Basically, a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. The machine was to be located near – specifically adjacent -- to the physical area of the pharmacy.

A number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive. A copy of the final regulation is provided below.

This regulation was promulgated cautiously. Throughout 2006, the board modified and adopted the regulation now in effect as section 1713. In January 2007, the regulation actually took effect.

During the meeting, the committee heard a presentation from Phil Burgess, representing Asteris, one vendor of these automated delivery devices. Mr. Burgess is seeking a waiver to the requirements in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. In making the request, Mr. Burgess stated that they would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist.

Mr. Burgess will provide a presentation to the board during the meeting.

A written copy of the waiver request as well as a copy of CCR 1713 is provided in **Attachment 1**. At the request of the committee, staff will be prepared to discuss various options for the board to consider.

2. FOR ACTION: Final Review of Parameters for Recalls in Hospitals

During the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall. The board cited and fined the hospital pharmacies and pharmacists-in-charge of these pharmacies. However, because many of these hospitals and PICs have appealed the citations and fines, board members cannot discuss the specific parameters of any of these cases without recusing themselves from voting on the specific case in the future should they be appealed to the Office of Administrative Hearings.

Over the last year, the board convened a two-board member task force to work with relevant associations, regulators, hospitals, wholesalers and patient advocates on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. Three meetings were held, and at the last meeting in September, a draft Best Practices document was refined. A draft document establishing the parameters for recalls in hospitals was one major outcome of these meetings.

The revised document will be provided during the board meeting. The last step will be a presentation to the board for ratification and future publication in the board's newsletter.

3. FOR INFORMATION: Emergency and Disaster Response Planning: Update on the H1N1 Emergency Response Activities in California

For more than one year, health care providers, policy makers and governments worldwide have been dealing with the H1N1 flu worldwide pandemic.

In California, the board has provided assistance. This has included:

- Sharing our subscriber alert system to advise licensees of directives from the California Department of Public Health
- Ensuring the expedited licensing of storage locations for the H1N1 vaccines
- Establishing a specialized list of compounding pharmacies that the Department of Public Health can access if special, compounded formulations of medications are needed
- Transferring messages from board licensees that need a response or intervention from the Department of Public Health's Emergency Planning and Response Branch, Emergency Preparedness Office

Board staff continues to work closely with the Department of Public Health to assist in ways that will benefit the public.

In order to ensure that the board can act quickly to activate the board's emergency response policy in response to a sudden declared crisis, at the October Board Meeting, the board voted that:

Agenda Item I(c)

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Item I (c): Request for a Waiver of Security Prescription Blank Prescribing Requirements for Controlled Substances in a Closed Health Care System

Background:

Existing law requires the use of security prescription forms for written prescriptions for controlled substances. Security prescription forms must be printed by state-registered printers and conform to specific requirements to make forgery of these forms difficult. There are few exceptions to the use of these specialized forms when a prescriber writes a prescription.

Schedule III-V drugs may be prescribed orally; only in very limited cases, may Schedule II drugs may be orally prescribed.

In 2010, the DEA released Interim Final Rules to permit the e-prescribing of controlled substances, and all e-prescriptions for controlled substances must the DEA's regulatory requirements, including a third-party audit of the computer application certifying that I meets the requirements of the DEA regulations.

E-prescribing is not faxing (where a prescription is actually written and signed by the prescriber, and a facsimile is transmitted to the pharmacy). Faxing is not allowed for controlled substances, although faxed prescriptions for Schedule III- V prescriptions are sometimes treated as oral prescriptions by pharmacies which if received, must verify the fax with the prescriber's office. (Note, a security prescription form, if faxed, is required to display a "VOID" impression on the faxed document, showing that the fax is not a legitimate written prescription.)

Request:

Kaiser Permanente has requested an opportunity to address the committee to seek an exemption within Kaiser's closed system of patient care to use plain paper to prescribe controlled substances. Their request is attached on the next page.

Representatives of Kaiser Permanente will appear at this meeting to provide the presentation.

Temporary Alternative Manual Process for Schedule III-V Prescriptions

Requested Kaiser Permanente Agenda Item
Board of Pharmacy Enforcement Committee March 14, 2013

Executive Summary. Kaiser Permanente (KP) has been reviewing our current manual system to process Schedule III-V controlled substance prescriptions. This review is in response to pharmacy, medical staff and member concerns about the impact of the current process on the quality of care and service we deliver in our pharmacies. In addition, there are concerns regarding the negative impact of the current manual process on the productivity of pharmacy, nursing and medical staff members, and thereby the cost to our patients, payors and the public. KP proposes to adopt a more secure method of processing Schedule III-V controlled substance prescriptions that takes advantage of its *Closed System of Prescribers and Proprietary Pharmacies* that share access to one electronic medical record (EMR) system in order to address these and other concerns.

Problem: The current manual process produces a Schedule III-V controlled substance prescription printed on plain paper printed from the KP EMR system. These prescriptions are subsequently hand signed and dated by the provider and faxed to a KP pharmacy. Though fully meeting DEA and California DOJ and BOP requirements, this method does cause delays in processing these prescriptions which negatively impacts the quality of care and service for our patients and ultimately generates unnecessary expense to our members and payors due to productivity issues. To address these issues long term, KP is pursuing an e-prescribing process for all prescriptions within our EMR and pharmacy systems. However, the current projected timeframe for vendor certification, pilot and program-wide implementation within California is likely at least 18 months away.

Proposed *Temporary* Alternative Manual Process: KP proposes a temporary alternative manual process, that is fully compliant with current DEA requirements. We would continue to print these prescriptions on plain paper from the KP EMR system and require the provider's original ink signature and date. However, instead of faxing these prescriptions to the KP pharmacy, we would instead provide the patient the original printed, signed and dated prescription for filling at a KP pharmacy. The KP pharmacy would then match this original prescription with the EMR order transmitted to the pharmacy system in order to be a valid prescription for filling and dispensing.

This proposed and more secure method will meet the objectives of the Secure Prescription Blank program, administered by the DOJ and described in Health and Safety Code Sections 11161.5 and 11162.1. In addition, it will also help to meet the objectives of H&S Code section 11164(b)(1) for ensuring the security, integrity, authority, and confidentiality of the prescription. Most importantly, it will help to address the quality of care, service, productivity, cost and other concerns with the current manual process. Representatives of the DOJ and others have expressed support with a recommendation to present this compliant temporary alternative process to the Board of Pharmacy for information.

Patients receiving a Schedule III-V prescription from a KP provider will still be able to fill the prescription at a non-KP pharmacy if they desire through the issuance of a secured personalized prescription or a verbal order to the non-KP pharmacy. Finally, upon the implementation of a certified e-prescribing system within KP, this temporary alternative manual process would be discontinued.

Agenda Item I(d)

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Item I(d): Board Comments on the Drug Enforcement Administration's Notice of Proposed Regulations Related to the Disposal of Controlled Substances

Background:

In 2009, California adopted guidelines for the take back and destruction of unwanted pharmaceuticals from the public so they could be appropriately destroyed and not misused by others or flushed down the drain. However, the guidelines were only guidelines until the FDA promulgated regulations to deal with the collection and destruction of controlled substances.

The DEA developed proposed regulations to deal with the take back and destruction of controlled substances and released them for comment in December 2012, with a final comment date of February 19, 2013. At the February Board Meeting, the board directed that comments be submitted to conform to board policy and California's guidelines in this area.

The board's are provided in Attachment Agenda Id. The general structure and components of the proposed regulations mirror to a high degree California's guidelines.

During this meeting, the committee will have an opportunity to discuss the board's comments and the proposed regulations. In the future, the board may wish to develop regulations to specify how pharmacies and reverse distributors handle unwanted drugs returned for destruction from the public.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

February 19, 2013

Drug Enforcement Administration

Docket No. DEA-316

Submitted electronically to http:www.regulations.gov

Dear Drug Enforcement Administration:

The California State Board State Board of Pharmacy is grateful for this opportunity to provide comments to the Drug Enforcement Administration on its proposal to establish parameters for the take back and destruction of unwanted controlled substances that have been dispensed to patients. We recognize the complexity of the task before the DEA in developing these regulations and we look forward to the enactment of the proposals, we hope with the several modifications we suggest below.

The California State Board of Pharmacy regulates nearly 140,000 licensees who dispense, store and ship prescription drugs and devices throughout, from and into California. This includes both individuals and firms including pharmacies, clinics, wholesalers, pharmacists and the designated representatives who are the licensed staff who work in wholesaler facilities. Under the general category of wholesaler, the board specifically licenses reverse distributors and brokers (who do not take possession but arrange for the sale of prescription medication).

California is the largest board of pharmacy in the US, and we work feverishly to secure our statutory mandate of consumer protection. In pursuit of this mandate, the board regulates the quality of the pharmaceutical products dispensed as well as the pharmacy services provided to patients. For a number of years, the appropriate disposal of prescription medication, coupled with escalating drug diversion and the growing prescription drug abuse problems have commanded the board's enforcement and educational efforts.

California is also at the forefront of issues surrounding the health of patients and possible jeopardy posed by unscrupulous "entrepreneurs," who buy and sell prescription drugs illegally and damage the state's (and nation's) drug supply. Patients and practitioners are ignorant of the potential for and presence of counterfeit or adulterated medication in the US pharmaceutical supply chain, and simply change therapy when a prescribed drug regimen no longer works.

Over the last decade, the board has aggressively undertaken innovative approaches to secure the quality of pharmaceuticals that are dispensed to patients in California. This includes:

- E-pedigree requirements to establish a comprehensive tracking system for the sale of each container of prescription medication dispensed to California patients, tracking and certifying ownership from the manufacturer, to the wholesaler, to the pharmacy or practitioner. Beginning in 2015 when the requirements become effective over a 2.5 year basis, e-pedigree requirements will permit the identification (and thus enable better investigation and prosecution) of suspect medication at the point it enters the pharmaceutical supply chain.

- Aggressive enforcement of financial sanctions for entities purchasing prescription medication from unlicensed sources ($5,000 per invoice, resulting in fines of hundreds of thousands of dollars).
- Issuance of fines to pharmacies filling internet prescriptions illegally where there is no legitimate prescription for the transaction ($25,000 per "prescription" dispensed, resulting of fines up to $100 million).
- Identification and discipline of pharmacies purchasing drugs not for dispensing to patients but exclusively for resale to wholesalers. Despite a specific prohibition in California enacted in 2004 to prevent a pharmacy from reselling medication to any wholesaler except for returns to the wholesaler that sold the pharmacy the medication initially, the board continues to identify new pharmacy practices involving such sales. Often these sales transactions involve medication in short supply, for which desperate providers and patients will pay high amounts. Such manipulation by pharmacies and wholesalers documented by the board has resulted in price increases to patients exceeding 6,000 percent.
- Hosting educational forums, jointly with the Drug Enforcement Administration, to educate pharmacists about the dangers of prescription drug abuse, drug diversion issues, corresponding responsibility and pharmacy robberies.
- Cooperative joint investigations of board licensees with the Drug Enforcement Administration and other law enforcement agencies to identify and prosecute criminal drug diversion, particularly involving controlled substances.

California has a considerable stake in addressing the disposal of prescription medication. With over 12 percent of the nation's population, 650 million prescriptions were dispensed to patients in California in 2011 out of the total of 4 billion prescriptions dispensed nationally that year. Not all of these medications would have been consumed -- leaving California with likely the largest unwanted drug disposal problems and issues in the country.

Today, there is a considerable illegal movement of prescription medication, including controlled substances, that has been dispensed to patients but ends up being returned/resold to pharmacies and wholesalers. These entities refill manufacturers' containers, and then resell these drugs into the drug supply where they are re-dispensed to unknowing patients. In recent years, the board has encountered multiple cases of this "recycling" in multiple California pharmacies. Often these drugs are obtained from skilled nursing facilities, where the facility and patients no longer have use for them, and destruction would cost the facility money. Instead pharmacies take these drugs back, remove them from blister packs and redispense or resell them.

We have disciplined multiple pharmacies for doing this, but are certain we have not discovered all pharmacies performing such activities. Obtaining drugs from such sources is considerably cheaper than purchasing drugs from legitimate sources. However, identifying such practices is quite difficult for a regulator. In the last two years, the FDA and other law enforcement agencies have identified at least three large scale "recycling" operations, where patients and others have resold dispensed medication back to brokers who repackage into manufacturers' containers and resell the products to wholesalers and pharmacies. We know that two of these three cases involve prescription drugs in California. Specifically:

- $250m worth of HIV medications in New York, some of which were likely shipped to and dispensed in California by a pharmacy linked in ownership with the New York pharmacies indicted

- $500m worth of HIV medications also in New York discovered by the NY AG's Office
- $498m worth of prescription drugs collected from California patients in a federal indictment filed in late 2012.

In 2008, pursuant to legislation enacted in California, guidelines for drug take back programs were developed by several state agencies, including this board. These policies could not be mandated until the Drug Enforcement Administration completed its work on the take back and destruction of controlled substances. In many ways, the Drug Enforcement Administration's proposed federal regulations for destruction of previously dispensed controlled substances support these California guidelines for drug take back programs, which encourage voluntary ongoing collection programs, special event collection, and mail back programs.

Our recommendations are in the form of general comments:

1. **We generally support the framework for the return and destruction of controlled substances as provided for in these proposed regulations. The growing prescription drug abuse and diversion issues in the US require action and such a regulatory framework.**
2. **We find no reference to brokering within the proposed regulations and believe that the proposed regulations do not permit brokering of previously dispensed controlled substances. However, we respectfully request that the DEA prohibit this activity specifically in these regulations. We believe that if left unchecked, the activities of brokers will complicate attempts to document and identify the activities of those entities handle the destruction of unwanted medication.**
3. **The board strongly supports the "commingling, do not sort" provisions of the proposed regulations. The sorting of pharmaceuticals collected in a drug take back program, when done by a pharmacy, reverse distributor or any entity poses a huge opportunity for diversion. In fact, we cannot envision another reason for sorting drugs except to secure a cache of specific drugs.**
4. **Regarding the non-retrievable method of destruction described in the general comments of the regulation package: we fully support commingling of prescription drugs with controlled drugs and even over the counter drugs at collection sites. We strongly support the prohibition against opening the collection devices and container linings, or sorting of collected pharmaceuticals.**

   However, the board now believes that the safest and surest way to ensure previously dispensed medication does not reenter the supply chain as a commercial product is to render the returned medication unusable: specifically to grind it up at the collection bin so that returned pharmaceuticals are nonsalable. As long as the medication can be differentiated as individual pills, it poses potential for being sorted and reintroduced into the supply chain. Grinders (like a coffee grinder or garbage disposal) could readily be added to collection bins at minimal expense to ensure no subsequent "recycling" occurs of the donation -- and in a manner that does not permit fingers to enter the grinding device.

   With implementation of such grinders, regulators can be less concerned that the collected drugs will again become part of the nation's drug supply, permitting redirection of limited enforcement staff to other diversion activities.

5. **We strongly urge that any pharmacy that agrees to accept drugs from nursing homes be required to similarly destroy and grind the medication at the time it is identified by the facility**

as unwanted waste. The attached photos taken during board investigations document issues we have discovered with drugs being returned to pharmacies where they are recycled to unknowing nursing home patients and other patients, principally from the large volume of medication targeted for destruction in these facilities.

Once a secure disposal system is developed, it could be made available to residential assisted living homes, where there is often no medical staff onsite, but drug disposal problems also exist.

Prescription drug abuse is a serious and growing problem in the US. We share the Drug Enforcement Administration's proposed requirements that reverse distributors, mail back programs, and collection programs offer the public options to dispose of unwanted pharmaceuticals, specifically the unique challenges of controlled substances. Yet from years of experience regulating pharmacies, wholesalers and reverse distributors, we do not want to see additional compromise in the quality of the state's and US pharmaceutical supply caused by opportunists who may pose as pharmacists, pharmacies, reverse distributors or others. The regulations proposed by the Drug Enforcement Administration are a good start. However, we respectfully assert that all drug take back programs involving previously dispensed medication should ensure the pulverization of medication returned so the remnants are worthless.

Thank you for this opportunity to comments on these important requirements. Please do not hesitate to contact the executive officer with questions.

Sincerely,

STAN WEISSER
President

Sincerely,

VIRGINIA HEROLD
Executive Officer

cc: Photos


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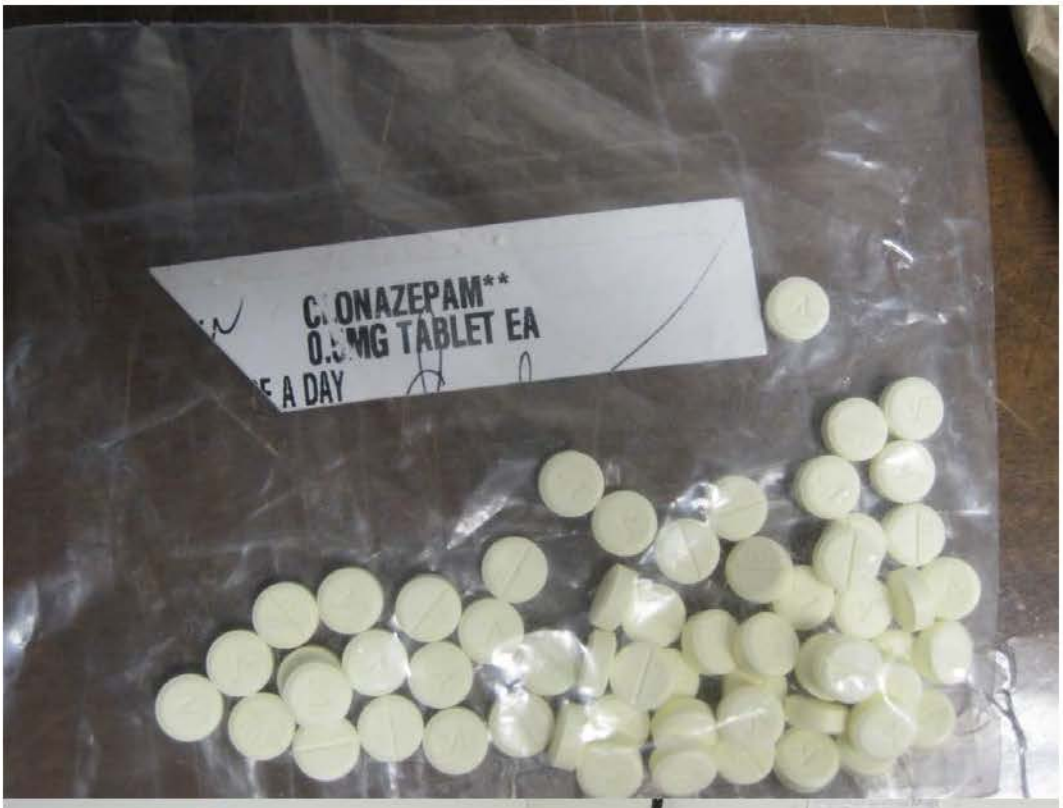
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Agenda Item I(e)

August 28, 2012

Senate Commerce Committee Report on Drug Shortages and the Gray Market "Where Have They All Gone"

Drug shortages continue to make the headlines in both mainstream media and on Capitol Hill. According to drug shortage tracking conducted by the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and the American Society of Health-System Pharmacists (ASHP), drug shortages more than quadrupled between 2005 and 2011. For example, CDER reported that drug shortages increased from 61 in 2005 to 251 in 2011.

FDA defines a drug shortage as "a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level."

To address this issue, Congress passed in July the Food and Drug Administration Safety and Innovation Act (FDASIA), which gives FDA significant new authorities to combat drug shortages, as we previously reported. While numerous causes for drug shortages have been identified, one serious problem remains: the "gray market." Consequently, the U.S. Senate Commerce, Science and Transportation Committee recently held a hearing and published a report addressing the gray market.

Background on Congressional Investigation

The rising number of drug shortages has been concentrated primarily in the area of generic sterile injectable drugs, liquids packaged in sterile glass vials that are

"parenterally" administered to the body through syringes or an intravenous (i.v.) administration set. Drugs administered in this manner reach their target treatment area more quickly than oral drugs, but also carry greater risks of infection and complications caused by incorrect dosages. Administering a drug intravenously usually requires a trained health care professional who can carefully monitor the dosage and the patient's reaction to the drug. As a result,

drug shortages are affecting mostly acute care patients being treated by providers in hospitals and out-patient facilities.

Of the 251 drug shortages the CDER reported in 2011, 182 of the shortages (73%) involved sterile injectables. An October 2011 analysis of short-supply drugs conducted by the IMS Institute for Healthcare Informatics also found that most of the reported shortages involved generic sterile injectable drugs. The largest numbers of drugs in this group (20) were sterile injectables used in chemotherapy treatment for cancer patients. The sterile injectables in shortage have also included frequently-used items such as anesthetics for surgery, "crash cart" drugs used in emergency rooms, and electrolytes for intravenous feeding.

In October 2011, House Committee on Oversight and Government Reform Ranking Member Elijah Cummings opened this investigation by sending information request letters to five "gray market" companies that were taking advantage of drug shortages to charge exorbitant prices for drugs used to treat cancer and other life-threatening conditions. These companies' questionable business practices put patients at risk and cost the United States health care system hundreds of millions of dollars each year.

During drug shortages, hospitals are sometimes unable to buy drugs from their normal trading partners, usually one of the three large national "primary" distributors, AmerisourceBergen, Cardinal Health, or McKesson. At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage drugs for prices that are often hundreds of times higher than the prices they normally pay.

The five companies were aggressively marketing five prescription drugs to hospitals that were at the time in short-supply, according to the FDA. Four of the drugs are used to treat various forms of cancer, and one is used to treat seizures during pregnancy. The letters asked the companies where they had obtained the short-supply drugs they were offering for sale and how much they were charging hospitals for the drugs.

In December 2011, Senator John D. Rockefeller IV, Chairman of the Senate Committee on Commerce, Science, and Transportation, and Senator Tom Harkin, Chairman of the Senate Health, Education, Labor, and Pensions Committee, joined Ranking Member Cummings in the investigation. Since that time, the three Members of Congress have requested information from more than 50 prescription drug industry experts, regulators, and stakeholders about how short-supply prescription drugs are distributed, marketed, and sold.

A key source of information in the investigation has been "drug pedigree" documents, which record the distribution route a drug has traveled since it left the manufacturer. Many businesses that distribute drugs in the United States are

required, either by state or federal laws, to provide these pedigrees to their customers.

Congressional investigators carefully studied 300 of these "paper pedigrees," which list the names of all parties that purportedly took possession of the drug and the dates of their possession. The 300 pedigrees show 125 different companies that were involved in selling short-supply prescription drugs. The Committee used the pedigrees to reconstruct how and when drugs entered gray market distribution chains and contacted companies listed in the pedigrees to collect information regarding the prices for which they purchased and re-sold the drugs. The Committee obtained specific information from the companies listed on 58 of the pedigrees, including the prices for which they purchased and sold the drugs and the dates they possessed them.

The drug "pedigree" documents showed that some short-supply injectable drugs "leak" into longer gray market distribution networks, in which a number of different companies – some doing business as pharmacies and some as distributors – buy and resell the drugs to each other before one of them finally sells the drugs to a hospital or other health care facility. In more than two-thirds (69%) of the 300 drug distribution chains reviewed in the investigation, prescription drugs leaked into the gray market through pharmacies. Instead of dispensing the drugs in accordance with their professional duties, state laws, and the expectations of their trading partners, these pharmacies re-sold the drugs to gray market wholesalers. Some pharmacies sold their entire inventories into the gray market. The wholesalers in turn sold the drugs − usually at significant markups − to other gray market companies.

Gray Market Companies Aggressively Mark Up Drug Prices

As the drugs pass through these gray market distribution chains, they are significantly marked up, sometimes to prices that are hundreds of times higher than the prices that hospitals and other health care providers normally pay. The markups in these chains often bear no relation to the companies' cost of purchasing, shipping, or storing the drugs. Instead, they reflect intent to take advantage of the acute demand for short supply drugs by charging health care providers exorbitant prices. Some companies marked up vials by more than 100%, even if they never took physical custody of the vials or only held them for a short time. The hospital that purchased the drug ended up paying $600 per vial for a drug that a pharmacy had purchased for $7 per vial. Hospitals purchase short-supply drugs at these exorbitant prices because, as one hospital explained, "We have no other choice … We have to take care of our patients." The investigation also found that:

- **"Fake Pharmacies" Acquire Prescription Drugs from Authorized Distributors and then Sell Them Into the Gray Market:** A number of businesses hold pharmacy licenses that do not dispense drugs, but

instead appear to operate for the sole purpose of acquiring short-supply drugs that can be sold into the gray market.

- **"Drug Brokers" Recruit Pharmacies to Purchase Drugs for the Gray Market.**
- **Gray Market Business Practices Are Widespread:** Pedigree and price information collected for five different short-supply injectable drugs, documenting the activities of 125 different companies, showed similar patterns of leakage and aggressive gray market price markups. For all five drugs, units normally costing $10 to $20 were regularly marked up to prices of $200 or more while they traveled through the gray market.
- **Gray Market Drugs Are Marked Up as They Quickly Pass from Owner to Owner.** On average, the prescription drugs examined in the investigation were owned by three to four different gray market businesses before being sold to a hospital; most of the drugs traveled through the gray market in five days or less.
- **Gray Market Companies Sometimes Charge Hospitals Significantly Different Prices for the Same Drug Product on the Same Day.**

The Appearance of Gray Market Companies

As a growing number of sterile injectable drugs went into short supply in 2010 and 2011, hospitals around the country began receiving increasing numbers of telephone, fax, and e-mail solicitations from "gray market" drug companies. These companies claimed to have supplies of short-supply drugs that the hospitals could not obtain through their normal distribution channels. The companies' offers generally mentioned the fact that the drugs were in short supply and often suggested that their supplies were very limited.

The gray market companies appeared to be taking advantage of supply shortages to sell the drugs at prices much higher than hospitals paid their normal suppliers. An analysis by the Premier Healthcare Alliance of 636 solicitations made to hospitals in early 2011 found that gray market companies were selling short-supply drugs at prices that were on average 650% higher than the prices hospitals paid for the drugs through their group purchasing agreements. In some cases, companies were selling the drugs at markups as high as 3,000% to 4,000% over their typical contract prices. In addition, some hospital pharmacists believe that gray market wholesalers contact them to learn which drugs the hospitals are having trouble acquiring so that the gray market wholesalers can quickly attempt to buy quantities of those drugs.

When the Institute for Safe Medication Practices (ISMP) surveyed a large group of hospitals in July and August 2011, it received hundreds of comments complaining about the gray market solicitations and asking "why hospitals can't get these products, but the 'scalpers' can." Hospital pharmacists also "reported feeling pressured by physicians and hospital administrators to purchase medications from the gray market."

Choosing between having no supply of a drug or purchasing the drug at an exorbitant price from an unknown gray market company raised difficult ethical and business questions for hospitals. Many hospitals and other stakeholders expressed concern about the safety of drugs purchased from gray market companies because they did not understand how gray market vendors obtain short-supply prescription drugs. Hospitals do not know where the drugs come from or if they were stored properly.

How Drug Distribution Chains Typically Work

A typical drug distribution chain has three elements: (1) a manufacturer, which creates and sells a prescription drug to (2) a wholesale distributor, which then sells the drug to (3) a hospital or pharmacy, which dispenses it to patients. In some cases, additional authorized parties might be involved in these chains. Drug manufacturers sometimes sell their products to "repackagers," before the drugs are distributed. In addition, large "primary" distributors sometimes sell drugs to "secondary" distributors, which then sell the drugs to pharmacies or hospitals. Such sales to secondary distributors comprise only a small percentage of primary distributors' sales.

Distributors that have an ongoing relationships with manufacturers serve as "authorized distributors of record" (ADR) for the manufacturers. About 85% of all revenues in the wholesale market are generated by three national distributors −AmerisourceBergen, Cardinal Health, and McKesson − that serve as ADRs for many manufacturers.

Distributors that predominantly buy prescription medicines from the manufacturers and predominantly distribute them directly to health care providers such as hospitals and pharmacies are called "primary" distributors. "Secondary" distributors are also sometimes ADRs, and they obtain access to drugs from primary distributors or other sources.

Distributors and pharmacies play distinct roles in the distribution chain and are subject to different regulatory and licensing requirements. Under federal law, distributors have the authority to purchase drugs from manufacturers and deliver them to pharmacies, hospitals, and other parties that are not patients. Pharmacies are the end point of the chain, responsible for dispensing the drug in a manner that is consistent with the appropriate treatment of a patient.

In addition to the obligations that come with their licenses as distributors or pharmacies, companies involved in drug distribution chains often also have contractual obligations to their trading partners. Most large distributors purchase drugs from manufacturers pursuant to ADR agreements, which sometimes restrict the distributors' freedom to buy and sell the drugs. The drug manufacturer Hospira, for example, requires its ADRs to commit that "they will

purchase Hospira products directly from Hospira, and only sell Hospira products to end users of our products."

Primary wholesale distributors commonly place similar "own use" restrictions on their customers. For example, one of the primary wholesale distributors requires most of its customers that hold themselves out as "Final Dispensers," such as pharmacies, to certify "that they do not and will not redistribute prescription pharmaceuticals purchased from [that primary wholesale distributor] into the Secondary Market." The same primary wholesale distributor also requires its secondary wholesaler customers to sell to "Final Dispensers" the pharmaceutical products they purchase from that primary wholesale distributor. Another primary wholesale distributor typically requires its final dispenser customers to agree to use purchased products for their "own use" and its secondary wholesaler customers to agree to sell purchased products only to final dispensers.

Ensuring that drugs pass through as few hands as possible on their way to patients helps to ensure the integrity and safety of the drug supply chain. According to the FDA, counterfeit drugs are most likely to be introduced as part of a drug supply chain involving multiple wholesalers.

Detailed Findings of Senate Report

1. Significant Markups Throughout Gray Market Distribution Chains. The Committee found that inflated prices were often the result of unnecessarily long distribution chains, diverted into longer "gray market" distribution networks that include significant markups at almost every level, often hundreds of times higher than the prices the hospitals and other health care providers normally paid for them.

2. Similar Results Found for All Five Shortage Drugs Examined. The pedigree and price information that was collected on the five sterile injectable drugs that were the subject of this investigation show a similar pattern.

3. Additional Information on Gray Market Chains. Some of the most significant results of this analysis were the following:

- In more than half of the transactions, prices for the drugs increased by $200 per unit or more while traveling through the gray market. In six chains, the price increase was $500 or more per unit. The largest increase was $975 per unit.
- On average, drugs traveling through these gray market chains were owned by three to four separate business entities before reaching the hospital or provider that administered the drugs to a patient.
- Most of the drugs traveling through the gray market (60.8%) were sold to hospitals within five days or less after they entered the gray market.55 In

13 chains, the drugs remained in the hands of gray market companies longer than 10 days.

The hospitals that purchased short-supply drugs through the 300 gray market chains staff reviewed include a range of small and large hospitals, urban and rural hospitals, for- profit hospitals, and military, veteran, and other nonprofit hospitals located in all regions of the United States. To estimate the financial impact that gray market purchases have on hospitals, congressional investigators compared actual gray market prices for one form of each of the five drugs reviewed to hospitals' contract price for the same drug product. The per-unit costs in the gray market were dramatically higher than the hospitals would have incurred to purchase the same drugs from their primary wholesale distributors:

Analysis revealed that hospitals overspent nearly $750,000 on over 2,100 units of the five prescription drugs examined as a result of purchasing the drugs from the gray market instead of their normal distributors. The more than 2,100 units included in this analysis are just a fraction of the total number of drug units that were sold in the 300 gray market chains.

How Drugs Enter the Gray Market

1. Drugs Entering Gray Market Primarily Through Pharmacies

2. Some Pharmacies Selling Their Entire Inventories into Gray Market. Evidence that some pharmacies are selling short-supply injectable drugs to gray market wholesalers suggests that these pharmacies are not complying with their states' pharmacy laws that limit re-sales. Some states allow pharmacies to re-sell portions of their inventories in emergency circumstances, while other states permit up to 5% of pharmacies' annual sales to come from re-selling their drugs. The parameters of these exceptions rules vary from state to state. Some states' rules appear to be intended to resolve local supply problems by allowing pharmacies to sell drugs to each other, while other states' rules may permit pharmacies to re-sell their drugs to wholesalers.

Documents obtained during the investigation indicate that some pharmacies are clearly exceeding these limited re-sale exceptions.

3. Using Pharmacies as Purchasing Agents for Shortage Drugs. Documents obtained during the investigation indicate that wholesalers and independent brokers often approached pharmacies and convinced them to purchase shortage drugs on their behalf, promising significant profits. Twenty-one of the 25 pharmacies that responded to requests for information about their purchases and sales of shortage drugs stated that wholesalers or brokers representing wholesalers had asked them to purchase shortage drugs for them.

Documents obtained during the investigation also reveal that brokers and consultants monitor the release of new drug shipments from manufacturers and their distributors. For example, on January 20, 2012, one broker sent an e-mail indicating that a new batch of metoprolol had been released, and asked various pharmacies to buy up the shortage drug, “we just [sic] found some it’s been a release find it get sale it [sic].”

Metoprolol is a drug used to improve survival after a heart attack and in the treatment of heart failure. Wholesalers operating in the gray market purchased a significant portion of prescription drugs through pharmacies.

4. Establishing Fake Pharmacies. Documents obtained during the investigation identified numerous entities that appear to have established “fake pharmacies” to gain greater access to shortage drugs. After obtaining these drugs, the “pharmacies” typically did not dispense the drugs to patients pursuant to their pharmacy licenses, but instead sold them to wholesalers they also owned or in which they had interests.

Gray market drug distributors sometimes cite shipping costs as one of the reasons they mark up the per unit price of the drugs they sell. But in many transactions examined in the investigation, the gray market companies billed shipping as a separate line item cost on their invoices. The shipping costs varied, but generally were less than $100 per invoice. In some transactions, the gray market companies never took physical possession of the drugs and instead arranged for drugs to be “drop shipped,” directly from the company from which they purchased the drugs, to the customer to which they sold them.

Agenda Item II(a-f)

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: Members, Enforcement Committee

Subject: Agenda Items II (a) –(f): Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

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II(a). Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 Has been Determined (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)

The board is completing its work on compiling the rulemaking file on these regulations. After this process is complete, the file will undergo the required review by administration agencies.

Copies of the final version of the regulation approved by the board are available from www.pharmacy.ca.gov and click under "laws and regulations."

II(b). Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule

During this part of the meeting, members of the supply chain can present information formally or informally, or ask questions of the committee involving their readiness to implement e-pedigree tracking and tracing. The board encourages such discussion as a way to foster better understanding, to speed and ease implementation, and to identify and resolve issues.

II(c). Discussion Concerning Elements for Possible Regulation Requirements to Permit Inference as Provided for by California Business and Professions Code Section 4163

Since July 2012, the board has several times released written requests seeking specific comments needed to develop possible regulations to authorize inference. The board has received only a few comments in response to these requests for information, and few of the comments received were appropriately responsive to the board's inquiries.

However, based on the information it has received, staff are working to develop proposed regulation requirements for inference for the committee's review. There will be discussion, and possible language, to foster this discussion at this meeting. Comments provided by the supply chain can be obtained from the December 4, 2012 Meeting Materials of the Enforcement Committee: http://www.pharmacy.ca.gov/about/meetings.shtml#enforce

II(d). Discussion on the Certification Process to Comply with California's e-Pedigree Law

At the December 2012 Enforcement Committee Meeting, there were specific questions asked about the certification processes that must be used when certifying sales or purchases of medication to append the e-pedigree. The committee will continue this discussion at this meeting.

II(e). Discussion on the Use of Drop Shipments in the e-Pedigree System

Recently staff released a solicitation request through the board's email notification system that the board was seeking information on drop shipments from members of the supply chain. The specific solicitation is provided as Attachment Agenda IIe.

In the short time since the release of this request, the board has not received any comments. Any comments received will be brought to the committee meeting.

II(f). General Discussion/Questions and Answers

The board remains highly interested in inquiries from the supply chain on implementation issues. At the close of this meeting, the committee will provide another opportunity for discussion.

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

March 5, 2013

To: All Interested Parties

Subject: Opportunity to Submit Information Necessary to Possible Board Rulemaking

On "Drop Shipment" and Certification of Individual Package Units
Drug Pedigree Law

Pursuant to Business and Professions Code section 4163.1 (see below), the Board of Pharmacy is confirming its willingness to receive information by written submission regarding supply chain participants' ability to use or rely on drop shipment(s) as an effective alternative process to convey the pedigree information for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law. (Bus. & Prof. Code, § 4034, 4163 et seq.)

To be considered for purposes of developing a possible future Board rulemaking on this subject, we request that all written submissions contain at minimum the information outlined below, and be received by mail or personal delivery at the Board offices by no later than March 12, 2013.

"*4163.1.(a) For purposes of Sections 4034 and 4163, "drop shipment" means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:*

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment."

Section 4163.1 specifies parameters within which the "drop shipment" conveyance of dangerous drugs by a manufacturer must comport in order to qualify as an alternative process for pedigree information transfer. The Board must relate any regulation establishing "drop shipment" as an alternative process for conveyance of pedigree information on the factors contained in the statute. Accordingly, the Board would benefit from supply chain members' input as to business circumstances utilizing the "drop shipment" model in order to craft and/or issue regulations under which it would be permissible as an alternative process as set forth in statute.

This notification confirms that the Board will accept written submissions from interested parties, in support of or in opposition to permitting drop shipment under specified circumstances, to develop the record necessary to any Board rulemaking on the subject of drop shipment and/or certification.[1]

Necessary Information in Submissions

Any submission by an interested party should include at least the following:

1. Identifying and contact information for the submitting person or entity.
2. A description of the submitting party's interest in this subject, including the submitting party's role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.
3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy that satisfactorily establishes the drop shipment model as an "alternative process for conveyance of pedigree information."
4. If the submitting party is seeking a regulatory allowance for drop shipment, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived or actual need for regulations to accommodate the drop shipment model. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which drop shipment might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the drop shipment process.
5. If the submitting party is opposed to a regulatory allowance for drop shipment, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.
6. The detailed reason(s) that drop shipment is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting or other risk(s) in the supply chain, holds risk(s) constant, or does not unacceptably increase such risk(s).
7. A schematic diagram to illustrate how the drop shipment works with respect to how the product moves and how the ownership transfers.

Where and When to Submit

All written submissions should be mailed or delivered to Executive Officer Virginia Herold, Board of Pharmacy, 1625 N. Market Blvd., Suite N219, Sacramento, CA 95834. Materials received on or before 12:00 Noon, Tuesday, March 12, 2013, will be considered by the Board in developing a possible rulemaking. These submissions will be considered at the Enforcement Committee meeting on March 14, 2013, and/or at the full Board meeting on April 24-25, 2013.

[1] The Board expects that submissions will be made primarily by individual persons, companies, or other entities that are themselves involved in the supply chain and able to supply information and data specific to their own operations regarding the potential benefits and risks of drop shipment. Although the Board also welcomes input from associations and other groups, it is most interested in the kind of detail that individual submissions can better provide. The Board is also interested in hearing from vendors, consultants, standards bodies, hardware and software providers, and other experts in the field, regarding their viewpoints on and experience(s) with the use of drop shipment.